K100976

T2 ALTITUDE™ Expandable Corpectomy System
510(k) Summary
October 18, 2010

I. **Company:**

Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

OCT 2 1 2010

Contact: Jennifer Hackney
Regulatory Affairs Specialist

II. Trade Name: T2 ALTITUDE™ Expandable Corpectomy System

III. Classification Name: Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)

IV. Product Code: MQP

V. **Description:** The T2 ALTITUDE™ Expandable Corpectomy System is a distractible system used in corpectomy procedures. This construct is inserted between two vertebral bodies in the thoracic and/or lumbar spine and is expanded to aid in the surgical correction and stabilization of the spine. The device may be implanted through a lateral or posterior approach using a minimally invasive technique or implanted through a lateral, posterior or anterior approach through a traditional open technique. T2 ALTITUDE™ Expandable Corpectomy System constructs may not be used with stainless steel supplemental fixation devices. The construct is not intended to be used as a stand alone device. Titanium constructs comprised from one of the following Medtronic spinal systems or their successors must be used with the T2 ALTITUDE™ Expandable Corpectomy System.

	Anterior	Posterior
VANTAGE® Anterior Fixation System	X	
TSRH® Spinal System	X	X
CD HORIZON® Spinal System	X	X

The T2 ALTITUDE™ Expandable Corpectomy System contains an expandable centerpiece, which is made of titanium alloy, cobalt chrome, and nitinol and is available in multiple diameters and heights to accommodate the patient's anatomical requirements. The T2 ALTITUDE™ Expandable Corpectomy System's optional end

caps may be attached to the T2 ALTITUDE™ Expandable Corpectomy System's expandable centerpieces as needed to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

VI. **Indications for Use:** The T2 ALTITUDE™ Expandable Corpectomy System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The T2 ALTITUDE™ Expandable Corpectomy Centerpiece may be used with or without optional modular endcaps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation. Specifically, the construct is to be used with the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, or their successors. Additionally, the T2 ALTITUDE™ Expandable Corpectomy System is intended to be used with allograft and/or autograft.

VII. **Substantial Equivalence**: Documentation was provided which demonstrated that the T2 ALTITUDE™ Expandable Corpectomy System components are substantially equivalent to previously cleared devices such as the T2 XVBR™ Spinal System K071033 (S.E. 08/14/2007), K082112 (S.E. 08/27/2008), and K091883 (S.E. 09/21/2009).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek, Inc.
% Ms. Jennifer Hackney
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

OCT 2 1 2010

Re: K100976
Trade/Device Name: T2 ALTITUDE™ Expandable Corpectomy System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: October 1, 2010
Received: October 4, 2010

Dear Ms. Hackney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OCT 2 1 2010

510(k) Number (if known): K100976

Device Name: T2 ALTITUDE™ Expandable Corpectomy System

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over-The-Counter Use _____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100976